C U – PH2

i-VIEWER

Operator's Manual

CardioMeter Series

Medical Systems, Inc.

CU Medical Systems, Inc.

Operator's Manual

i-VIEWER CU-PH2 ver 1.00

Medical Systems, Inc.

OPERATOR'S MANUAL

Version 1.00

Notice:

This Operator's Manual applies to i-VIEWER CU-PH2, the portable ECG and SPO2 monitoring equipment from CU Medical Systems, Inc. The information contained in this manual is subject to change without prior notice.

Copyright

Copyright © 2006
CU Medical Systems, Inc.
Medical Instrument Industry Park
1720-26 Taejang-Dong,
Wonju-Si, Kangwon-Do
Korea

This document may not be reproduced without prior written consent of CU Medical Systems, Inc.

Medical Systems, Inc.

Table of Contents

Table of Contents 4
General 6
Warranty 7
Service Request 8
Contact Us 9

1. How to Use This Manual 10
1.1 Contents of This Manual 10
1. 2 Safety Messages 11

2. Device Operation Guidelines 12
2.1 Storage and Operating Environment Guidelines 12
2.2 Notes On Electrical Safety 14
2.3 Cleaning and Maintenance 15

3. Introduction 16
3.1 Product Description 16
3.1.1 Controls and Ports 17
3.1.2 ACCESSORIES 20
3.1.3 Optional Accessories 22
3.2 Intended Use 23

4. Operating Controls, Indicators, Ports, And Accessories 23
4.1 Operating Controls 23
4.2 Indicator Lamps 24
4.3 Ports 24
4.4 Equipment Symbols 25

5. OPERATION 26
5.1 Unpacking 26
5.1.1 Battery Installation 26
5.2 Screen Display 27
5.3 User Interface 29
5.3.1 Device Setting Submenu 29
5.3.2 Monitoring Setting 33
5.3.3 Record Review 35
5.3.4 Save And Exit 38
5.4 Using The i-Viewer CU-PH2 39
5.4.1 ECG Acquisition Using the 3 Electrode ECG Cable Assembly 39
Step 1: Preparation 39
Device Preparation 39
User/Patient Preparation 39
Step 2: Ecg Signal Acquisition 41
5.4.2 ECG Acquisition Using the 5 Electrode ECG Cable Assembly 42
5.4.3 SPO2 Monitoring 43
Pulse Oximetry Sensors 44
Application and Connection of the Sensor 45
SPO2 Monitoring 45
SPO2 Monitoring Notes and Warnings 46

6. Maintenance And Troubleshooting 48
6.1 Maintenance 48
6.2 Cleaning The i-Viewer CU-PH2 50
6.3 Troubleshooting Guide 50
6.4 Device Life 51

7. Safety Considerations 52

8. Data Management And Review 55

9. Specifications 56

General

Thank you for choosing the i-Viewer CU-PH2. Please read this Operator's Manual carefully and thoroughly before using the i-Viewer CU-PH2. This Manual contains instructions on how to operate and maintain the i-Viewer CU-PH2. The features of the i-Viewer CU-PH2 are all discussed in this Manual.

It is very important for you to fully understand all the instructions and guidelines discussed in this Manual in order to fully utilize the features of this device and to ensure safe operation.

CU Medical Systems, Inc. designs and manufactures all its products in accordance with international standards (NS-EN ISO9001:2000/ ISO13485:1996-MDD 93/42/EEC). This ensures that CU Medical Systems, Inc. provides products of high quality and reliability. In this regard:

- **Only persons authorized by CU Medical Systems, Inc. must do all servicing of the device.**
- **You must ensure that the correct batteries are properly installed before using this device.**
- **You must operate this device in accordance with the instructions specified in this manual.**

To ensure safety and reliability, use only parts and accessories recommended by CU Medical Systems, Inc.

Warranty

- ✍ The products of CU Medical Systems, Inc. are designed and manufactured according to international standards (NS-EN ISO9001:2000/ ISO13485:1996-MDD 93/42/EEC).

  Every device that goes out of the assembly line passes through a battery of reliability tests. In case of problems, our maintenance and exchange policies are in accordance with the relevant consumer protection laws and regulations of the particular country where this device is sold.
- ✍ The warranty period of this device is within two years after the date of purchase.
- ✍ When the device malfunctions during the warranty period, it will be repaired free of charge at our service centers.
- ✍ When you submit the device for maintenance, please specify the details as listed below :

  The device model, serial number, date of purchase, name of sales representative, customer information and a brief description of the problems.

<table>
<tr><td>Name of Product</td><td colspan="4">CardioMeter</td></tr>
<tr><td>Model</td><td colspan="2">i-Viewer CU-PH2</td><td>Serial No.</td><td></td></tr>
<tr><td>Date of Purchase</td><td colspan="2"></td><td>Sales Representative</td><td></td></tr>
<tr><td rowspan="3">Customer Information</td><td>Name</td><td colspan="3"></td></tr>
<tr><td>Address</td><td colspan="3"></td></tr>
<tr><td>Contact No.</td><td colspan="3"></td></tr>
<tr><td>Brief Description of Problems</td><td colspan="4"></td></tr>
</table>

Service Request

Only CU Medical Systems, Inc. or its authorized representatives should service the device. If the device is serviced by unauthorized personnel during the warranty period, the warranty will become null and void.

CU Medical Systems, Inc. or its authorized representatives are obliged to service the device free of charge during the warranty period. Damage to the device incurred beyond normal use is not covered by the warranty.

When the device is not functioning properly, it has to be submitted for maintenance immediately.

When any problems are found in the device or when a danger to bodily harm exists, the device has to be repaired immediately by authorized personnel.

When the need for maintenance arises:

- ✍ Please contact CU Medical Systems, Inc. or its authorized representatives immediately. Prepare a summary of the problems.

✍ Contact Us

You can contact us at the following address and telephone number for services and supplies.

Product and Order Inquiries:

International Marketing Team
CU Medical Systems, Inc.
Medical Instrument Industry Park
1720-26 Taejang-Dong, Wonju-Si, Kangwon-Do
Korea
Tel : +82 33 747 7657
Fax : +82 33 747 7659
email address: sales@cu911.com

Service Request and Technical Support

Customer Service Team
CU Medical Systems, Inc.
Medical Instrument Industry Park
1720-26 Taejang-Dong, Wonju-Si, Kangwon-Do
Korea
Tel : +82 33 747 7657
Fax : +82 33 747 7659
email address: service@cu911.com

Our website:
http://www.cu911.com

Authorized European Representative of CU Medical Systems, Inc.

A.M.I Italia s.r.l
Via Cupa Reginella N 17A
80010 Quarto (Napoli) Italy
Tel No 0039 (0) 81 806 34 75
0039 (0) 81 806 34 75
Fax No 0039 (0) 81 876 47 69
Email: info@amitaliasrl.it
Website: www.amitaliasrl.it

1 How to Use This Manual

1.1 Contents of This Manual

✍ This Operator's Manual contains all the information a user needs to operate the i-Viewer CU-PH2 properly. The i-Viewer CU-PH2 is designed to acquire, display, and extract the heart rate of the ECG of a patient/user. The i-Viewer CU-PH2 is also equipped with the capability to monitor the SPO2 of a patient.

✍ In case you have any problems regarding the operation of the device, please don't hesitate to contact us.

✍ Specifications and information in this manual are subject to change without prior notice.

1. 2 Safety Messages

Safety messages are used throughout this manual to emphasize important things that must be followed during the operation of the i-Viewer CU-PH2. You must follow the instructions in all the Warnings, Cautions, and Notice messages found throughout this Operator's Manual

In the event that the product is damaged due to misuse or negligence by a user, the manufacturer or its authorized representatives shall not be responsible for the said damage or loss to the product.

⚠WARNING

Conditions, hazards, or unsafe practices that can result in serious personal injury.

⚠CAUTION

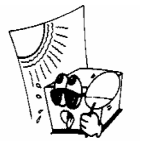
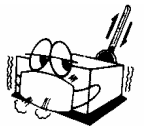
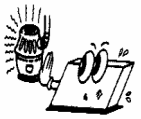
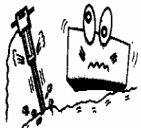
Conditions, hazards, or unsafe practices that can result in minor personal injury, damage to the CU-PH2, or loss of data stored in the device.

NOTICE

These messages are used to denote items that are important during installation, operation, or maintenance of the device.

2 Device Operation Guidelines

2.1 Storage and Operating Environment Guidelines

	Do not operate or store the device in conditions that are beyond the following specified limits. Operating Conditions Temperature 0 °C to 50 °C Humidity 5 % to 95 % (non-condensing) Storage Conditions Temperature -20 °C to 70 °C Humidity 5 % to 95 % (non-condensing)
	Do not store the device in areas that are directly exposed to sunlight
	Do not store the device in areas with highly fluctuating temperatures
	Do not store the device near heating equipment
	Do not store the device in areas where there is high vibration (in excess of Category 10 of MIL-STD-810E)
	Do not operate or store the device in areas with high concentration of dust
	Only personnel authorized by the manufacturer shall open the device for servicing.

The following are the general guidelines in storage and operating environment conditions.

- Do not expose the device to direct sunlight during storage.
- Do not store the device in locations with temperature and humidity conditions that are beyond the specified safe range
  Temperature: -20°C to 70°C
  Relative Humidity: 5% to 95% (non-condensing)
- Do not store the device close to heating equipment and appliances.
- Do not store the device near sources of vibration.
- Do not store and operate the device in locations that are exposed to chemicals, explosive gas and solvents.
- Keep the device away from dusty environments.
- There are no user serviceable parts inside the i-Viewer CU-PH2. Only authorized service personnel should open the device for repairs.

The Standard Operating Conditions are as Follows:

- **Temperature: 0 °C to 50 °C**
- **Relative Humidity: 5 % to 95 % (non-condensing)**

The standard storage and shipping conditions are as follows:

- **Temperature: -20 °C to 70 °C**
- **Relative Humidity : 5 % to 95 % (non-condensing)**

2.2 Notes On Electrical Safety

⚠WARNING

During operation, the device should be placed away from sources of electromagnetic interference such as motors, generators, X-Ray equipment, radio transmitters, cellular mobile telephones and others, as these might interfere with the signals being acquired.

NOTICE

The i-Viewer CU-PH2 is classified as follows:

- **It is a Class I, Type CF equipment in terms of electrical shock prevention (EN 60601-1). It is not proper to operate this device around combustible anesthetic or solvents.**
- **The noise level is "B" Class according to EN 60601-1 (Safety of Electric Medical Equipment), and the noise redemption is "B" level according to the EN 60601-1-2 (Electromagnetic Compatibility Requirements).**

2.3 Cleaning and Maintenance

When the case is contaminated with dirt, clean the i-Viewer CU-PH2 using a soft, damp cloth moistened with any of the following solvents:

Soap and water
70% solution isopropyl alcohol
Chlorine bleach and water mixture (30 ml bleach/liter of water)
Ammonia-based cleaners
Hydrogen peroxide

⚠CAUTION

Do not immerse any part of the i-Viewer CU-PH2 in fluids.
Do not let any fluid enter the case of the device.
Do not spill liquids on the case of the device.
Do not use strong, acetone-based cleaners in cleaning the device.
Do not use abrasive materials in cleaning the unit, especially the LCD display and the infrared filter on the IrDA port.
Do not sterilize the i-Viewer CU-PH2.

Although there are no user serviceable parts inside the i-Viewer CU-PH2, you can do some maintenance check that will help ensure that the device stays in mint condition.

- ✍ Check the case of the device for any apparent damage.
- ✍ Check the ports (ECG connector port) to see that it is tightly in place.
- ✍ Check the accessories, especially the ECG electrodes, to see that they are in good condition and that they have not yet reached their expiration dates.

NOTICE

A more comprehensive maintenance routine is discussed in the chapter on Maintenance of this User's Manual.

3. INTRODUCTION

3.1 PRODUCT DESCRIPTION

The i-Viewer CU-PH2 is a lightweight, portable, battery operated, 5-lead Electrocardiogram (ECG) and SPO2 monitoring device.

It has a high resolution (320x240 pixels) liquid crystal display (LCD). One of the leads and the plethysmographic wave is displayed simultaneously.

The i-Viewer CU-PH2 runs on four AAA size 1.5V batteries. It may also run using a supplied AC/DC adapter.

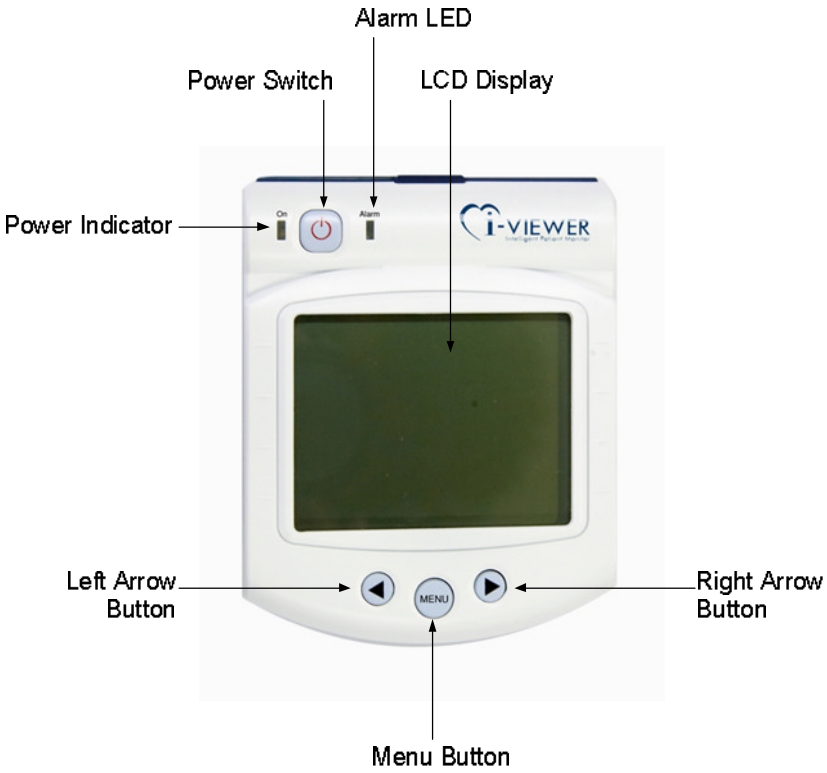
ECG signal acquisition is achieved through a five-electrode ECG acquisition assembly with disposable electrodes while SPO2 signal acquisition is done using the recommended Nellcor SPO2 Sensors.

User interaction is through three function buttons (LEFT, RIGHT, and MENU). Through these buttons, the settings of the device can be changed.

ECG signals can be recorded in the internal nonvolatile memory of the device. The stored signals can later be reviewed. These recorded signals can also be transferred to a personal computer that is running the CU Expert ECG Data Management Software. The CU Expert is available as an option.

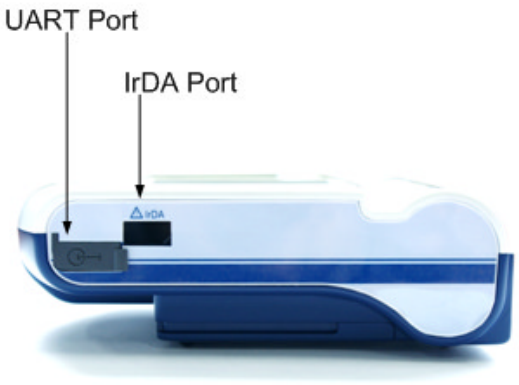
The i-Viewer CU-PH2 analyzes the signal it acquires from the user and determines the heart rate of the user. The device prompts the user through the beeper and the LED alarm indicator if it detects an abnormal heart rate. Abnormal heart rate is any heart rate beyond the normal limits defined by the user.

3.1.1 Controls and Ports



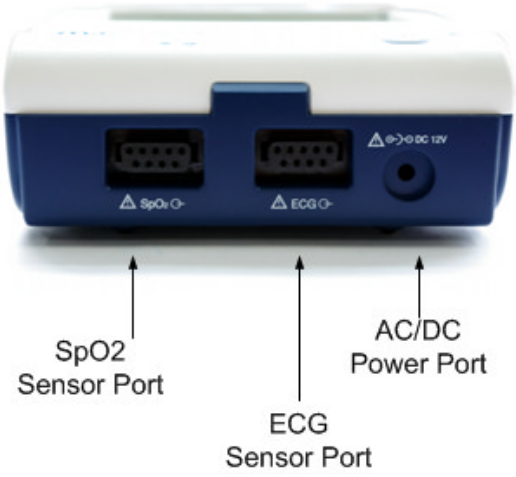
i-Viewer CU-PH2 top view

Power indicator	Green LED, lit when the device is ON.
Power switch	Used to turn the device ON or OFF
Alarm LED	Red LED, flashes when the device detects an ECG signal with beat rate that is beyond the normal range defined by the user.
LCD display	Displays the following: a. ECG signal acquired from the patient b. ECG signal recorded in the memory of the device c. Plethysmographic wave of the patient. d. Menu e. Device settings
LEFT arrow button	Used to scroll the menu highlight to the left or upward. This button is also used to change the Lead of the ECG signal being acquired.
MENU button	Used to activate the menu. When the menu is activated, it is used to select the highlighted menu item
RIGHT arrow button	Used to scroll the menu highlight to the right or downward. This button is also used to turn the QRS beeper ON or OFF



i-Viewer CU-PH2 right side view

IrDA port	used to transmit data from the i-Viewer CU-PH2 to a personal computer using an IrDA transmission.
UART port	used to transmit data from the i-Viewer CU-PH2 to a personal computer using serial wired connection.



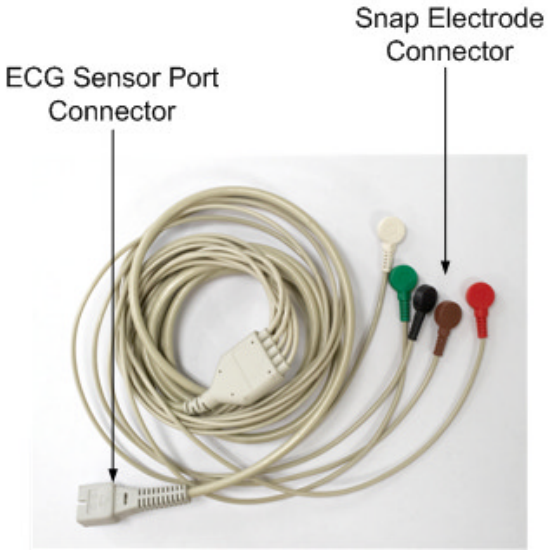
i-Viewer CU-PH2 back side view

SpO2 Sensor Port	used to connect the SpO2 sensor to the i-VIEWER CU-PH2
ECG Sensor Port	used to connect the ECG electrode assembly to the i-VIEWER CU-PH2
AC/DC Power Port	used to connect the AC/DC adapter to the i-VIEWER CU-PH2

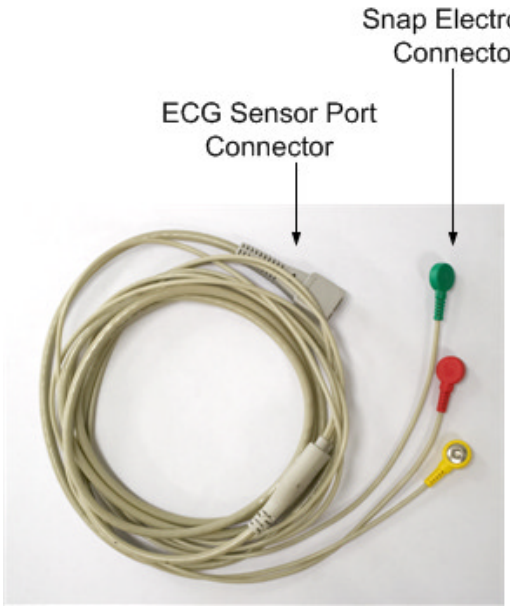
i-Viewer CU-PH2 Bottom View

Battery Cover	covers the battery compartment. The battery compartment contains the four AA batteries that are used to power the device.

3.1.2 ACCESSORIES

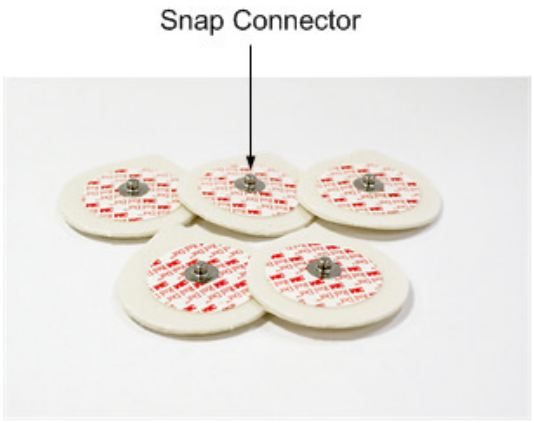


5-electrode Cable and Connector Assembly



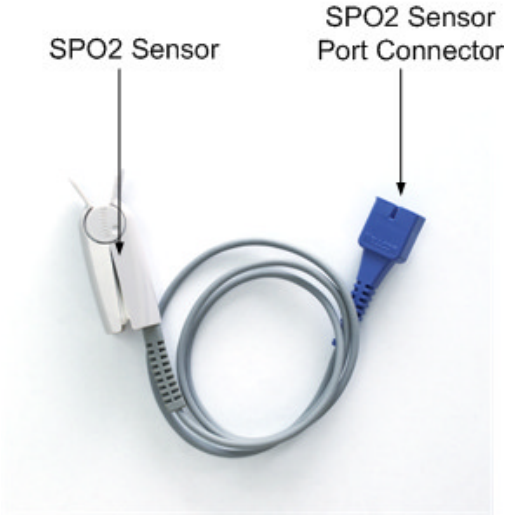
3-electrode Cable and Connector Assembly

ECG Sensor Port Connector	used to connect the cable and connector assembly to the i-Viewer CU-PH2
Snap Electrode Connector	used to connect the cable and connector assembly to the disposable ECG electrodes.



Disposable ECG Electrodes

Snap Connector	used to connect the electrode to the cable assembly



SPO2 Sensor Assembly

SPO2 Sensor	used to acquire the SPO2 signal from the patient
SPO2 Sensor Port Connector	used to connect the sensor assembly to the SPO2 sensor port on the i-Viewer CU-PH2

3.1.3 Optional Accessories

- Leather Case
- Cradle
- CU Expert Patient Management Software
- IrDA Cable
- UART Cable

3.2 INTENDED USE

The i-Viewer CU-PH2 is intended for ECG and SPO2 signal monitoring.

It is intended for the continuous non-invasive monitoring of ECG, functional oxygen saturation of arterial hemoglobin (SPO2) and pulse rate. It is intended for use with neonatal, pediatric, and adult patients during both no motion and motion conditions and for patients who are well or poorly perfused, in hospitals, hospital-type facilities, intra-hospital transport, and home environments. For prescription use only.

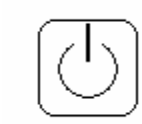
NOTICE

Hospital use typically covers such areas as general care floors, operation rooms, special procedure areas, intensive and critical care areas, within the hospital plus hospital-type facilities. Hospital-type facilities include physician office based facilities, sleep labs, skilled nursing facilities, surgicenters, and sub-acute centers.

Intra-hospital transport includes transport of a patient witching the hospital or hospital-type facility. Home Care use is defined as managed/used by a lay person (parent or other similar non-critical caregiver) in the home environment.

4. OPERATING CONTROLS, INDICATORS, PORTS, AND ACCESSORIES

4.1 OPERATING CONTROLS

 **ON / OFF Switch**	Turns the power of the **i-Viewer CU-PH2** ON or OFF.
LEFT BUTTON	a. Scrolls the Menu highlight UP or to the LEFT b. Scrolls the ECG record to the left (displaying the earlier parts of a recorded ECG) during RECORD REVIEW c. Changes the ECG Lead acquired by the device when pressed during ECG acquisition.
RIGHT BUTTON	a. Scrolls the Menu highlight DOWN or to the RIGHT b. scrolls the ECG record to the right (displaying the later parts of a recorded ECG) during RECORD REVIEW c. Turns the QRS beep ON or OFF
MENU BUTTON	Used to activate the menu select an item during menu operation.

4.2 INDICATOR LAMPS

POWER ON LED	When ON, indicates that the i-Viewer CU-PH2 is ON. This LED is colored green
ALARM LED	When ON, indicates an abnormal ECG or SPO2. This is used together with the beeper. This LED is colored RED

4.3 PORTS

ECG Sensor Port	used to connect the ECG electrode assembly to the i-Viewer CU-PH2
SPO2 Sensor Port	used to connect the SpO2 sensor to the i-Viewer CU-PH2
IrDA PORT	used to transmit data from the i-Viewer CU-PH2 to a personal computer using an IrDA transmission.
UART PORT	used to transmit data from the i-Viewer CU-PH2 to a personal computer using serial wired connection.
AC/DC Power port	used to connect the AC/DC adapter to the i-Viewer CU-PH2

4.4 Equipment Symbols

	Power ON/OFF Switch
	Attention, consult accompanying documents
	Date of manufacture
	Signal transfer port
IrDA	Infrared data communications port
	Battery state :displayed on LCD screen
	Symbol of data recording: displayed on LCD screen.
	QRS beeper state indicator: displayed on LCD screen.

5. OPERATION

5.1 UNPACKING

Upon receiving the device:

1) Carefully inspect the packing container for any apparent damage.
2) Inspect the unit for apparent damage that it might have sustained during shipping.
3) Check the shipping list to ensure that the unit comes with the complete accessories.

5.1.1 Battery Installation

The battery compartment cover of the i-Viewer CU-PH2 is located at its bottom side. Slide the cover as indicated (see the bottom view figure in section 3.1) The i-Viewer CU-PH2 needs four (4) 1.5V AA size batteries. The polarities are shown inside the battery compartment.

NOTICE

Avoid storing the batteries at extreme temperatures. Batteries perform best when stored and used between –15 °C and 55 °C

NOTICE

Keep batteries in low humidity locations with low temperature variations.

NOTICE

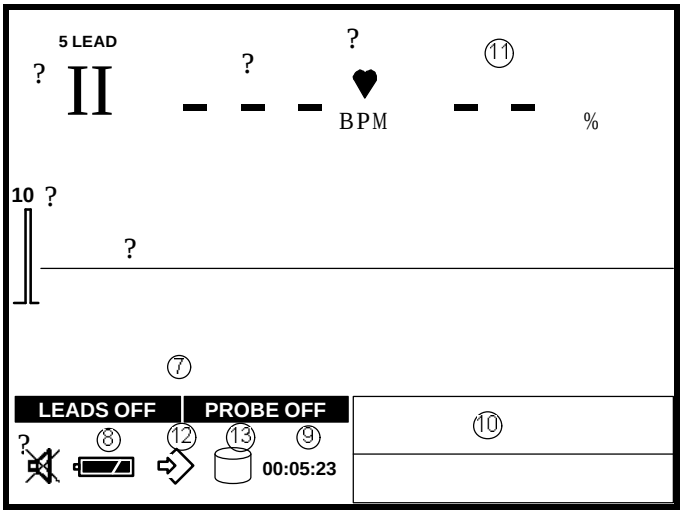
Keep batteries away from direct sunlight.

NOTICE

Do not attempt to recharge non rechargeable batteries.

5.2 SCREEN DISPLAY

Upon turning the device ON, it will display the screen shown below



Screen Display of the i-Viewer CU-PH2

?	LEAD	Indicates the lead number of the ECG signal being displayed
	States	I – indicates that LEAD I bipolar limb lead is being displayed
		II - indicates that LEAD II bipolar limb lead is being displayed
		III - indicates that LEAD III bipolar limb lead is being displayed
		aVR – indicates that LEAD aVR is being displayed.
		aVL - indicates that LEAD aVL is being displayed.
		aVF - indicates that LEAD aVF is being displayed.
		V - indicates that LEAD V is being displayed.
?	BPM source and QRS detection	Indicates the source of the BPM value calculation and the detection of QRS waves in the acquired ECG signal
	States	♥ Displayed – the source of the BPM calculation is the ECG signal
		Not displayed – the source of the BPM calculation is the SPO2 signal.
		♥ heart icon is not flashing– indicates that no QRS wave is detected
		♥ heart icon is flashing - indicates that QRS wave is detected. Heart icon alternates between small and large sizes to simulate heart beat display
?	BPM display	Displays the heart rate (in bpm) of the acquired ECG signal or the pulse rate of the acquired SPO2 signal
	States	BPM rate is displayed when it falls within the limits of 30 and 300 bpm
		––– is displayed when the heart rate is beyond the limits of 30 and 300 bpm
?	QRS beep	Turns the QRS-synchronized beep ON or OFF
	States	indicates that the QRS-synchronized beep is ON
		indicates that the QRS-synchronized beep is OFF
?	ECG Gain	Indicates the gain setting of the ECG display in mm/mV
	States	5 the ECG is displayed with a 5 mm/mV gain
		10 the ECG is displayed with a 10 mm/mV gain
		20 the ECG is displayed with a 20 mm/mV gain
		A the ECG is displayed with autoscaled gain. When the peak to peak value of the acquired signal is within 0.3 mV to 1 mV, the ECG is displayed using 10mm/mV. When the acquired signal is beyond the range 0.3 mV to 1 mV, the peak to peak value is displayed as 10 mm on the LCD screen.

Screen display continued

9	Main display	Displays the acquired signal from the user. This may either be the ECG or the plethysmographic wave.
	States	Displays ECG signal in the range 0.05mV to 5.5 mV
		Displays the plethysmographic wave of the patient.
7	Sensor connection status	Indicates when the leads or the SPO2 probe is OFF.
	States	Displays the prompt “LEAD FAULT”
8	Battery State Indicator	Indicates the charge status of the batteries The battery life is determined using Duracell batteries.
	States	indicates that the battery has full charge. In this state, the battery can run the device continuously for approximately 5 hours
		indicates that the battery has medium charge. In this state, the battery can run the device continuously for approximately 3 hours
		indicates that the battery has low charge. In this state, the battery can operate for approximately one hour
		indicates that the battery is almost empty. In this state, the battery can run the device continuously for approximately 15 minutes more. When the battery is empty, the prompt “BATTERY IS EMPTY” is displayed at the center of the LCD screen.
		indicates that the i-Viewer CU-PH2 is powered using the AC/DC adapter.
9	Time	Displays the time elapsed since the device was turned ON. Format is hours: minutes:seconds
	States	The elapsed time from 00:00:00 to 99:59:59 is displayed. If the device is ON beyond 99:59:59, the display wraps around to 00:00:00
10	Plethysmographic wave display	Displays the plethysmographic wave of the patient
	States	Plethysmographic wave display if both ECG and plethysmographic wave are displayed.
		Alarm limits if only the ECG or the plethysmographic wave is displayed.
11	SPO2 Value	Displays the SPO2 value of the patient.
	States	70% to 100% SPO2 value
12	Recording indicator	Indicates the recording status of the i-Viewer CU-PH2
	States	recording is ongoing
		No recording; memory is full.
13	Memory space indicator	Indicates the availability of memory space.
	States	Not displayed: Memory space is available
		Displayed and flashing: 9 out of 10 memory partitions are used up and there is memory for at most 2 hours of recording time.

5.3 USER INTERFACE

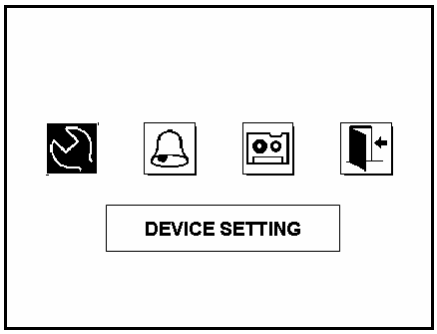
The menu is activated by pushing the MENU button. The highlight can be scrolled sideways or up and down by pushing the RIGHT or LEFT button. The submenu field values are scrolled by pressing the MENU button. The heart rate and SPO2 limit values are incremented/decremented using the RIGHT or LEFT buttons.

For example, to change the BACKLIGHT settings, highlight the BACKLIGHT option and then cycle through the choices (ON, OFF, 5 SEC) by pressing the MENU button repeatedly. When the desired setting is selected, effect the change by moving the highlight away from the BACKLIGHT option using the RIGHT or LEFT key.

There are four main MENU items. These are:

a. Device Setting – enables the user to change device configuration
b. Monitoring Setting – enables the user to change ECG and SPO2 acquisition parameters.
c. Record Review – enables the user to review the recorded ECG signals. The average bpm trend can also be tracked under the Review submenu.
d. Save and Exit – used to exit from the MENU and go back to the ECG display screen.

When the MENU button is pushed while the device is ON, the following is displayed:

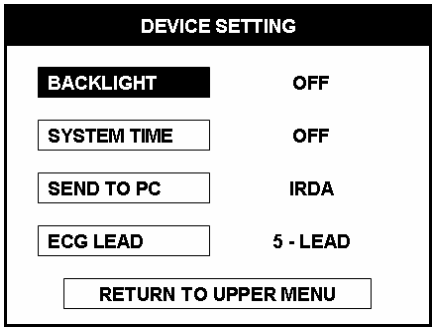


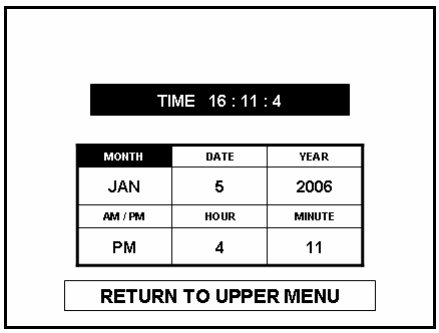
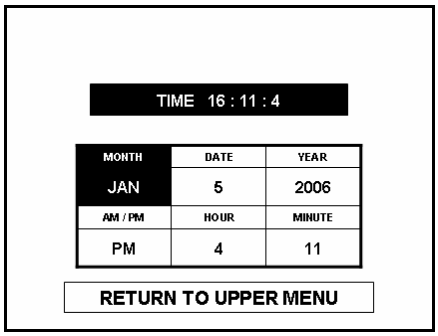
The arrow buttons can be used to scroll the highlight across the main menu items: DEVICE SETTING, MONITORING SETTING, RECORD REVIEW, and SAVE AND EXIT. When the RIGHT arrow button is pushed, the highlight scrolls to the right. When the LEFT arrow button is pushed, the highlight scrolls to the left.

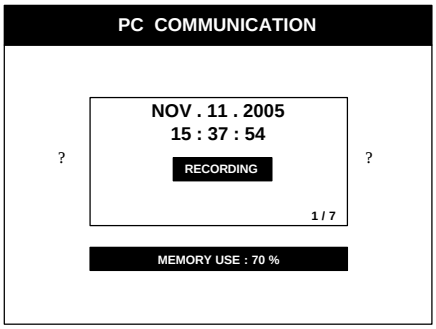
5.3.1 DEVICE SETTING SUBMENU

When the MENU button is pushed while DEVICE SETTING is highlighted, the menu goes one level down and the highlight can be scrolled up and down from BACKLIGHT to RETURN TO UPPER MENU. Any sub item is entered by pushing the MENU button while the sub item is highlighted.

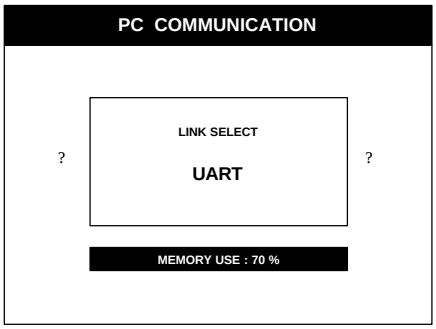
DEVICE SETTING SUBMENU ITEMS

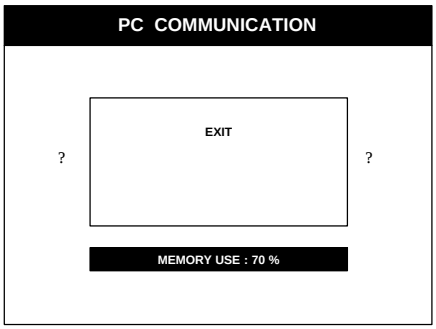


Submenu Item	Settings	
BACKLIGHT	ON	The backlight is always ON. Setting is changed by pressing the MENU button.
	OFF	The backlight is always OFF
	5 SEC	The backlight is ON for 5 seconds when any key is activated (LEFT ARROW, MENU, RIGHT ARROW). The backlight turns OFF after 5 seconds.
SYSTEM TIME	Pressing the MENU button while SYSTEM TIME is highlighted displays the following:  Pressing the RIGHT or LEFT button cycles the highlight through MONTH – DAY – YEAR – AM/PM – HOUR – MINUTE – RETURN TO UPPER MENU	
	 Pressing the MENU button while any of the date variables is highlighted enables the user to change the date or time variable. Values are changed by pressing the LEFT or RIGHT button. After the variable is set, the user must press the MENU button to go one level higher in the menu subsystem.	

<table>
<tr><th>Submenu Item</th><th colspan="2">Settings</th></tr>
<tr><td rowspan="3">SEND TO PC</td><td colspan="2">Pressing the MENU button while SEND TO PC is highlighted displays the following:
 

Pressing the RIGHT or LEFT button cycles the screen through all the recordings, the LINK SELECT screen and the EXIT screen.

Pressing the MENU button while any of the recording summaries is displayed sends the recording to the PC.</td></tr>
<tr><td colspan="2"> 

Pressing the MENU button while the LINK SELECT screen cycles the setting between IrDA and UART.</td></tr>
<tr><td colspan="2"> 

Pressing the MENU button while the EXIT screen is displayed takes the MENU to one sublevel higher.</td></tr>
<tr><td rowspan="2">ECG LEAD</td><td>5 LEAD</td><td>The PH2 is capable of displaying Leads I, II, III, aVR, aVL, aVF, and V. Setting is changed by pressing the MENU button.</td></tr>
<tr><td>3 LEAD</td><td>The PH2 is capable of displaying Leads I, II, and III</td></tr>
</table>

NOTICE

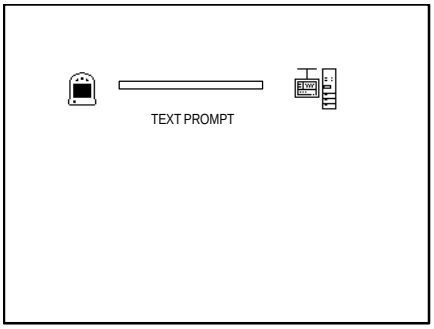
The backlight draws a considerable amount of power. When it is on, the battery will be depleted faster than when the backlight is disabled.
It is recommended that the backlight be turned ON only when absolutely necessary e.g. device operation in dark places

Data Transmission to a Personal Computer

Data is transmitted to a personal computer using the IrDA Com Port Serial Adapter or the UART cable. The CU Expert ECG Data Management Software must also be running on the PC during data transmission (see CU Expert User's Manual).

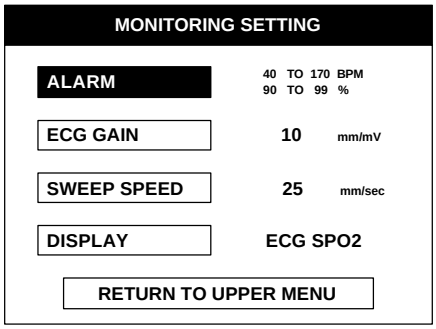
To transfer data to a personal computer, do the following steps.

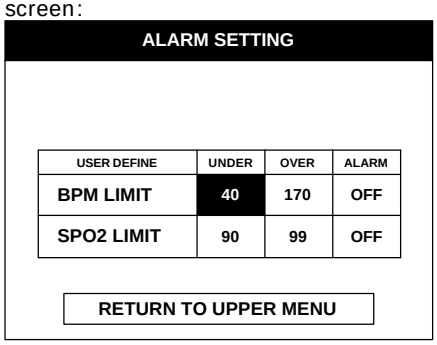
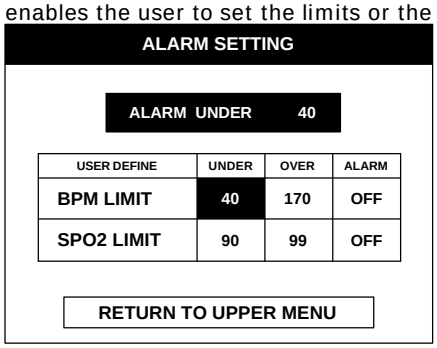
1. Connect the IrDA Com Port Serial Adapter or the UART cable to the COM 1 or COM 2 port of the PC.
2. If the IrDA port is used, align the IrDA transceiver of the IrDA Com Port Serial Adapter to the IrDA port of the i-Viewer CU-PH2. If the UART port is used, connect the UART cable to the ECG/UART port of the i-Viewer CU-PH2.
3. Open the CU Expert ECG Data Management Software in the PC. Set the options in accordance with the instructions given in its User's Manual. Make the connection by performing the following step:
   - Open the serial port and click the OK button in the dialog that prompts for the reception to begin.
4. In the i-Viewer CU-PH2, set the appropriate PC link (UART or IrDA).
5. Choose the recording to be transmitted and begin transmission by pressing the MENU button.
6. When transmission begins, the following screen is displayed in the LCD display of the i-Viewer CU-PH2



7. The text prompts indicate the status of the data transmission. The following are the text prompts that the i-Viewer CU-PH2 displays.
   a. PREPARING FOR TRANSMISSION – the i-Viewer CU-PH2 is preparing for transmission
   b. TRANSFERRING DATA – data is being transferred through the IrDA port
   c. TRANSMISSION COMPLETE – the data transmission is finished
   d. TRANSMISSION ERROR OCCURRED – the data transfer failed
8. As the data transfer proceeds, the data transfer progress will be shown through the progress bar. When the transmission is finished, the "TRANSMISSION COMPLETE" text prompt is displayed.
9. After the data transmission is finished, turn OFF the i-Viewer CU-PH2.

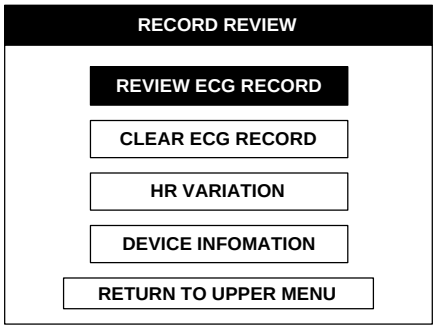
5.3.2 MONITORING SETTING

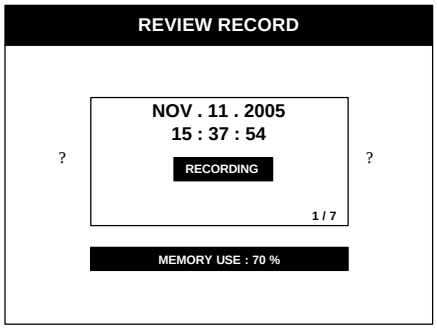
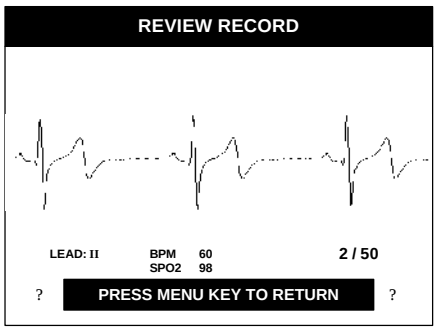


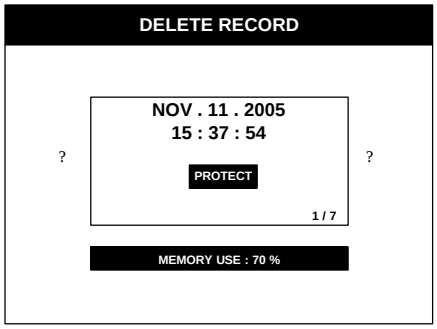
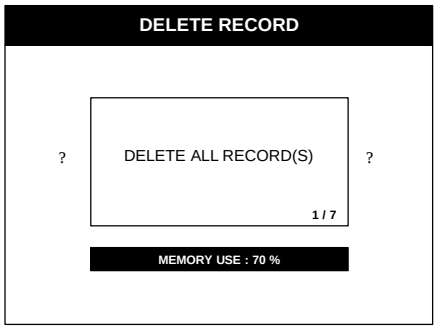
Submenu Item	Settings
ALARM	Pressing the MENU button while ALARM is highlighted displays the following screen:  The screen enables the user to set the limits of the ALARM system of the i-Viewer CU-PH2. Pressing the RIGHT or LEFT button cycles the highlight through lower limit, upper limit, and alarm status of ECG and SPO2 alarms.
	Pressing the MENU button while one of the limits or the alarm status is highlighted enables the user to set the limits or the status.  The limits are set by pressing the RIGHT or LEFT button while the alarm status is set by pressing the MENU button.

Submenu Item	Settings	
ECG GAIN	5 mm/mV	The ECG signal is displayed with a 5 mm/mV gain. Setting is changed by pressing the MENU button.
	10 mm/mV	The ECG signal is displayed with a 10 mm/mV gain.
	20 mm/mV	The ECG signal is displayed with a 20 mm/mV gain.
	AUTO	ECG is displayed with autoscaled gain. When the peak to peak value of the acquired signal is within 0.3 mV to 1 mV, the ECG is displayed using 10mm/mV. When the acquired signal is beyond the range 0.3 mV to 1 mV, the peak to peak value is displayed as 10 mm on the LCD screen.
SWEEP SPEED	25 mm/s	The ECG is displayed with a time base of 25 mm/s. Setting is changed by pressing the MENU button.
	50 mm/s	The ECG is displayed with a time base of 50 mm/s.
DISPLAY	ECG SPO2	The ECG waveform is displayed on the main display while the plethysmographic wave is displayed on the plethysmographic display.
	ECG FIRST	The ECG waveform is displayed on the main display while the alarm limits are displayed on the plethysmographic display.
	SPO2 FIRST	The plethysmographic waveform is displayed on the main display while the alarm limits are displayed on the plethysmographic display.

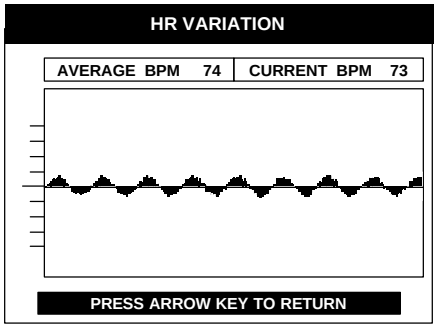
5.3.3 RECORD REVIEW



Submenu Item	Settings
REVIEW ECG RECORD	Pressing the MENU button while REVIEW ECG RECORD is highlighted displays the following screen that contains record summary:  Pressing the RIGHT or LEFT button cycles the screen through all the recordings and the EXIT screen. Pressing the MENU button while any of the recording summaries is displayed displays the ECG recording for review. This is shown in the following figure:  Pressing the MENU button while the EXIT screen is displayed takes the MENU to one sublevel higher.

Submenu Item	Settings
CLEAR ECG RECORD	Pressing the MENU button while REVIEW ECG RECORD is highlighted displays the following screen that contains record summary:  Pressing the RIGHT or LEFT button cycles the screen through all the recordings, the DELETE ALL RECORDS and the EXIT screen. Pressing the MENU button while any of the recording summaries is displayed deletes the particular ECG record from the memory. Pressing the MENU button while the DELETE ALL RECORD(S) screen is displayed, deletes all the ECG recording in the memory of the i-Viewer CU-PH2. The screen is shown in the following figure:  Pressing the MENU button while the EXIT screen is displayed takes the MENU to one sublevel higher.

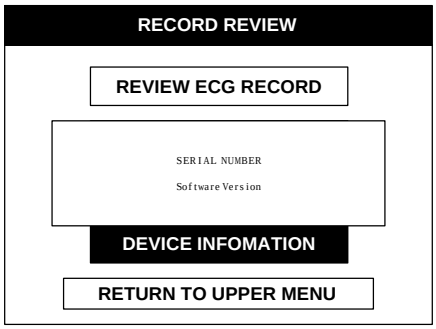
HR VARIATION



HR VARIATION shows the variation of heart rate over time. The average BPM and the current BPM values are shown on the screen.

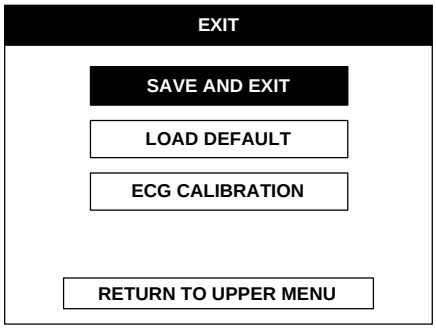
The graph's horizontal axis represents the average BPM. Each marking on the vertical scale is equal to 10 BPM.

DEVICE INFORMATION



DEVICE INFORMATION indicates the Serial Number of the device and the version of its software.

5.3.4 SAVE AND EXIT



<table>
<tr><td>Submenu Item</td><td>Settings</td></tr>
<tr><td>SAVE AND EXIT</td><td>When the MENU button is pressed while this is highlighted, all the changes done when the MENU operation is entered are saved and thus, these become effective.</td></tr>
<tr><td>LOAD DEFAULT</td><td>When the MENU button is pressed while this is highlighted, the factory default settings are loaded and become effective. These settings are shown below:
<table>
<tr><td>BACKLIGHT</td><td>OFF</td><td>ECG GAIN</td><td>10 mm/mV</td></tr>
<tr><td>ECG LEAD</td><td>5 LEAD</td><td>SWEEP SPEED</td><td>25 mm/sec</td></tr>
<tr><td>BPM LIMIT</td><td>40 TO 170 (OFF)</td><td>DISPLAY</td><td>ECG SPO2</td></tr>
<tr><td>SPO2 LIMIT</td><td>85 TO 100 (OFF)</td><td></td><td></td></tr>
</table></td></tr>
<tr><td>ECG CALIBRATION</td><td>When the MENU button is pressed while this is highlighted, the ECG subsystem of the i-Viewer CU-PH2 is calibrated.</td></tr>
</table>

5.4 USING THE i-Viewer CU-PH2

5.4.1 ECG Acquisition Using the 3 Electrode ECG Cable Assembly

Step 1: Preparation

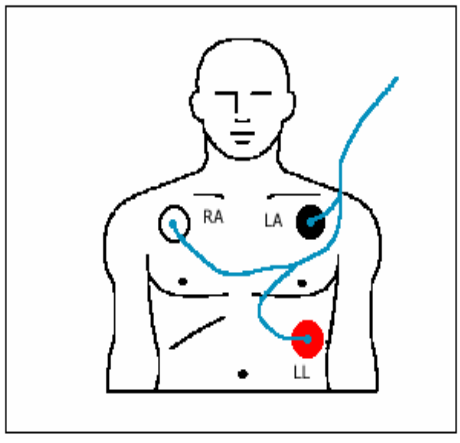
Device Preparation:

Every time you use the i-Viewer CU-PH2:

1. Inspect the physical condition of the device. Ensure that the case, the control buttons, and the ECG port are in good condition.
2. Inspect the ECG cable and connector assembly. Ensure that the cable insulation and the connectors on both ends (electrode side and i-Viewer CU-PH2 side) are not damaged.
3. Make sure that you have the proper electrodes. Electrodes should be in good condition. They must not be past their expiration date. Ensure that the conducting gel has not dried out. **Do not reuse disposable electrodes**.

User/Patient Preparation

1. Ensure that the areas where the electrodes will be attached are free of moisture, grease, or dirt. See the figure below for the position of the electrodes
2. Shave excessive hair.
3. Remove the protective plastic backing of the disposable electrodes. Make sure that the conducting gel has not dried out. Place the electrodes in the positions indicated in the figure below.
4. Ensure that the cable and connector assembly is connected properly. Check for any apparent damage in the cable and connector assembly. The lead connectors should be properly connected to the trunk cable. The connections are color-coded. RA is colored RED, LA is colored YELLOW, and LL is colored GREEN.
5. Attach the electrode connectors to the corresponding electrodes.
6. Attach the other end of the trunk cable to the ECG input port of the i-Viewer CU-PH2.
7. Turn the device ON.



Electrode positions

NOTICE

Make sure that the disposable electrodes are not yet past their expiration date. Do not use electrodes that are past their expiration dates.

NOTICE

If you are using electrodes that are packaged in a pouch, close and reseal the pouch after getting the electrodes that you need. Resealing the packaging pouch will help prolong the life of the electrodes.

NOTICE

Do not reuse disposable electrodes. These are for one time use only.

NOTICE

Some electrode conducting gel may cause skin irritation on some patients/users. If this occurs, switch to electrodes with different conducting gel.

NOTICE

The i-Viewer CU-PH2 may be left on the patient during defibrillation. The device is defibrillation protected.

Step 2: ECG SIGNAL ACQUISITION

As soon as the i-Viewer CU-PH2 is properly connected to the patient and turned ON, it will begin ECG signal acquisition and ECG display. It will also automatically begin recording the data in its internal memory.

NOTICE

During ECG data acquisition, the patient or user should keep still to avoid having motion artifacts in the ECG signal. Motion artifact is caused by electrical interference from muscular activity.

As long as the i-Viewer CU-PH2 is acquiring ECG signal, it will do analysis and will indicate the heart rate (in bpm). It will also prompt the user through the alarm beeper if the ECG it has acquired is abnormal. Abnormal ECG is ECG that has a rate outside the range defined by the user.

NOTICE

The CU-PH2 will indicate only the heart rate (in bpm) and whether the ECG signal is normal or not. It will not analyze the ECG signal for arrhythmias or other heart abnormalities.

NOTICE

The CU-PH2 is capable of acquiring any of the leads (Leads I, II, III, aVL, aVF, aVL, and V) without having the position of the electrodes changed. However, only the chosen lead is acquired, analyzed, and recorded at any given time.

⚠CAUTION

Do not short the electrodes when the device is ON.

⚠WARNING

If the i-Viewer CU-PH2 is powered by the AC/DC adapter, do not use the it alongside with high frequency electrocautery equipment. The i-Viewer CU-PH2 may be used alongside with high frequency electrocautery equipment if it is powered by batteries.

⚠WARNING

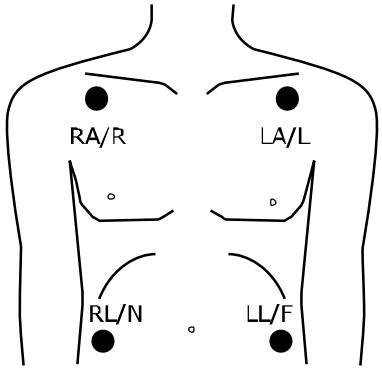
The device is designed to be used only in the acquisition and processing/display of surface ECGs. The device is not to be used in direct cardiac application (i.e. applied directly to the heart during open chest operations)

NOTICE

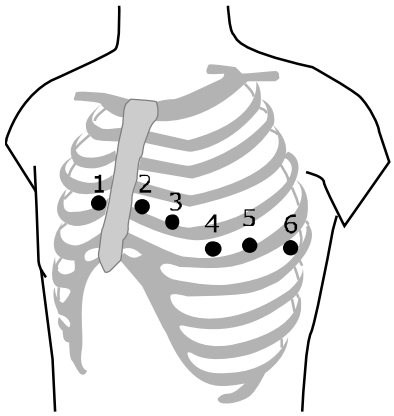
The device will issue a "LEADS OFF" text prompt on the LCD when the leads are off. The leads are off when the pads are not properly connected or the cable and connector assembly is damaged

5.4.2 ECG Acquisition Using the 5 Electrode ECG Cable Assembly

The 5-electrode ECG Cable Assembly can be used by placing the electrodes in the following positions:



Placement of the RA, LA, LL, and RL electrodes



Lead		Location
V1	C1	forth intercostal space, at right sternal margin
V2	C2	forth intercostal space, at left sternal margin
V3	C3	midway between V2/C2 and V4/C4
V4	C4	fifth intercostal space, at left midclavicular line
V5	C5	same level as V4/C4, on anterior axillary line
V6	C6	same level as V4/C4, at left mid axillary line

Placement of the V electrode

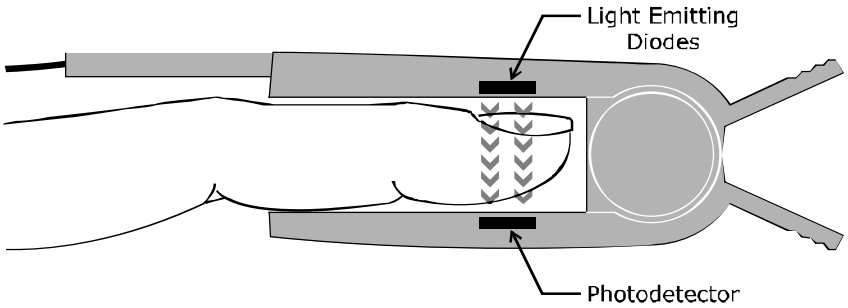
The following table shows the leads that can be displayed by the device when the 5-electrode ECG cable assembly is used.

Lead	Lead Formation
I	LA - RA
II	LL - RA
III	LL - LA
aVR	$RA - \frac{LA + LL}{2}$
aVF	$LL - \frac{RA + LA}{2}$
aVL	$LA - \frac{RA + LL}{2}$
V_x	$V/C - \frac{RA + LA + LL}{3}$

5.4.3 SPO2 Monitoring

The i-Viewer CU-PH2 is fitted with a Nellcor SPO2 Module.

The SPO2 Module measures functional oxygen saturation in the blood. The measurement determines the oxygenated hemoglobin as a percentage of the hemoglobin that can transport oxygen.



Pulse oximetry works by having light emitting diodes pass red and infra-red light into arteriolar vascular beds such as a finger or a toe and having the light detected by a photo detector afterwards.

Bone, tissue, pigmentation, and venous vessels normally absorb a constant amount of light over time. The arteriolar bed normally pulsates and absorbs variable amounts of light during the pulsations. The ratio of light absorbed is translated into a measurement of functional oxygen saturation (SpO2).

Pulse oximetry is based on two principles: that oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (spectrophotometry), and that the volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (plethysmography). A pulse oximeter determines SpO2 by passing red and infrared light into an arteriolar bed and measuring changes in light absorption during the pulsatile cycle. Red and infrared low-voltage light-emitting diodes (LED) in the oximetry *OXIMAX* sensor serve as light sources; a photo diode serves as the photo detector.

Because oxyhemoglobin and deoxyhemoglobin differ in light absorption, the amount of red and infrared light absorbed by blood is related to hemoglobin oxygen saturation. To identify the oxygen saturation of arterial hemoglobin, the monitor uses the pulsatile nature of arterial flow. During systole, a new pulse of a rterial blood enters the vascular bed, and blood volume and light absorption incre ase. During diastole, blood volume and light absorption reach their lowest point. The pulse oximeter bases its SpO2 measurements on the difference between maxi mum and minimum absorption (measurements at systole and diastole). By doing so, it focuses on light absorption by pulsatile arterial blood, eliminating the effect s of nonpulsatile absorbers such as tissue, bone, and venous blood. *

*excerpt from Oximax N-595 Pulse Oximeter Operator's Manual
Nellcor Puritan Bennett, Inc.

Pulse Oximetry Sensors

The i-Viewer CU-PH2 comes with a DS100A reusable Nellcor sensor that is meant to be used with a finger of the patient.

Other sensors from Nellcor may also be used with the i-Viewer CU-PH2.

The following table shows the all the Nellcor Oximetry sensors that may be used with the i-Viewer CU-PH2. Choose the sensors to suit the weight of the patient.

Sensor	Type	Patient	Patient Size	Ideal Site
MAX FAST®	disposable	Pediatric Adult	> 10 kg	forehead
MAX A®	disposable	Adult	> 30 kg	Index finger
MAX AL®	disposable	Adult	> 30 kg	Index finger
MAX P®	disposable	Pediatric	10-50 kg	Index finger
MAX I®	disposable	Infant	3-20 kg	Great toe
MAX N®	disposable	Neonatal Adult	<3 kg Or >40 kg	Neonatal – ball of the foot Adult – index finger
MAX R®	disposable	adult	>50 kg	nose
DURA Y®	Reusable	Neonate Pediatric Adult	> 1 kg	Adult (>40kg) index finger Pediatric (15-40kg) index finger Infant (3-15kg) great toe Neonate (1-3kg) ball of the foot
DYSE EAR CLIP	Reusable	adult	> 30 kg	Ear lobe and pinna
DYSPD PED CLIP	Reusable	Pediatric	3 to 40 kg	Index finger
DS100A®	Reusable	adult	> 40 kg	Index finger

Reusable sensors may be reused on different patients after cleaning and disinfecting.
Disposable sensors may be used only once.

NOTICE

Only Nellcor SPO2 sensors (Oximax) are compatible with the Nellcor SPO2 module of the Paramedic CU-ER3.

Do not use any other sensors aside from the ones recommended.

WARNING

Before using, carefully read the OxiMax sensor directions for use, including all warnings, cautions, and instructions.

Application and Connection of the Sensor

Apply the sensor to the site specified in the table above

Connect the sensor cable to the SPO2 Sensor Port as shown in the following figure:

As soon as the SPO2 Cable is connected, the i-Viewer CU-PH2 acquires the SPO2 signal of the patient.

SPO2 Monitoring

The plethysmographic wave of the patient may be displayed on the screen choosing ECG SPO2 or SPO2 FIRST in the MONITORING SETTING Submenu.

Set the alarm limits as described in the ALARM submenu of MONITORING SETTING.

SPO2 Monitoring Notes and Warnings

- The SPO2 module in the i-Viewer CU-PH2 measures functional oxygen saturation – oxygenated hemoglobin expressed as a percentage of the hemoglobin that can transport oxygen.
- The range of the peak wavelengths and maximum optical power are stated in the Specifications found in the Appendices of this Operator's Manual. This is useful to clinicians performing therapies that are using light emissions (e.g. photodynamic therapy)

⚠WARNING

Do not rely solely on SPO2 readings. The SPO2 module of the i-Viewer CU-PH2 is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.

⚠WARNING

Failure to cover the SPO2 sensor site with opaque material in high ambient light conditions may result in inaccurate measurements.

⚠WARNING

As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.

⚠WARNING

Disconnect the i-Viewer CU-PH2 and the SPO2 sensor from the patient during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns.

⚠WARNING

Do not use SPO2 sensor or cable that appear damaged.

⚠WARNING

The SPO2 sensor may remain attached to the patient during defibrillation or while an electrosurgical unit is in use, but the SPO2 readings may be inaccurate during defibrillation and shortly thereafter.

⚠WARNING

Physiological conditions, medical procedures, or external agents that may interfere with the monitor's ability to detect and display measurements include dysfunctional hemoglobin, arterial dyes, low perfusion, dark pigment and externally applied coloring agents, such as nail polish, dye, or pigmented cream.

⚠WARNING

Each time the i-Viewer CU-PH2 is used to monitor SPO2, check alarm limits to ensure that they are appropriate for the patient being monitored.

⚠WARNING

Do not attach any cable that is intended for computer use to the SPO2 sensor port of the i-Viewer CU-PH2.

⚠WARNING

Tissue damage can be caused by incorrect application or duration of use of an SPO2 OxiMax sensor. Inspect the OxiMax sensor site periodically as directed in the OxiMax sensor directions for use.

⚠WARNING

Do not immerse or wet the OxiMax sensor.

⚠WARNING

If you are uncertain about the accuracy of any measurement, check the patient's vital signs by alternate means; then make sure the pulse oximeter is functioning properly.

⚠WARNING

To get an accurate reading, see to it that there is no excessive motion from the patient and that the sensor is applied properly.

⚠WARNING

Do not place the sensor on an extremity that has a blood pressure cuff, arterial catheter, or intravascular line.

6. MAINTENANCE AND TROUBLESHOOTING

6.1 MAINTENANCE

There are no user-serviceable parts inside the i-Viewer CU-PH2. However, the user can do simple maintenance tasks that will help prolong the life of the device.

The following are the activities, together with their frequencies, that the user can do.

NOTICE

Used consumables (disposable electrodes, batteries) must be disposed of in accordance with local regulations

⚠CAUTION

Turn the device OFF before removing the batteries during battery replacement

Maintenance Activities

Activity	Actions to be Taken
Check the battery level indicator on the LCD display.	If a message that the battery is low is displayed, replace the batteries. The i-Viewer CU-PH2 runs on 4 AA size batteries. The device should be turned OFF before the batteries are removed.
Check the expiration date of the disposable electrodes.	If the electrodes are beyond their expiration date, replace them immediately. Dispose of the expired electrodes in accordance with local regulations.
Check the case of the i-Viewer **CU-PH2** and the accessories for any sign of apparent damage. Check for dirt contamination.	If there is any apparent damage to the case of the device, consult the manufacturer. If there is dirt contamination, clean the case as suggested in the section on Cleaning of this Manual.
When not in use, turn the device OFF to prolong the life of its batteries.	

6.2 CLEANING THE i-Viewer CU-PH2

If the case is contaminated with dirt, clean the I-VIEWER CU-PH2 using a soft, damp cloth moistened with any of the following solvents:

Soap and water
Chlorine bleach and water mixture (30 ml bleach/liter of water)
Ammonia-based cleaners
Hydrogen peroxide

⚠CAUTION

Do not immerse any part of the i-Viewer CU-PH2 in fluids
Do not let any fluid enter the case of the device.
Do not spill liquids on the case of the device.
Do not use strong, acetone-based cleaners in cleaning the device.
Do not use abrasive materials in cleaning the unit, especially on the LCD display and the infrared filter on the IrDA port.
Do not sterilize the CU-PH2.

6.3 TROUBLESHOOTING GUIDE

⚠WARNING

There are no user-serviceable parts inside the i-Viewer CU-PH2. For those conditions not specified in this troubleshooting guide, please consult the manufacturer or its authorized representatives.

⚠WARNING

The manufacturer will not be liable for any damage or injury that may arise from an attempt to repair the device beyond what is described in this troubleshooting guide.

NOTICE

Attempts to repair the i-Viewer CU-PH2 beyond what is described in this troubleshooting guide will make the warranty null and void.

SYMPTOMS/CONDITIONS	CAUSE(S)/POSSIBLE CAUSE(S)	ACTION(S) TO BE TAKEN
Low Battery Indicator ON	Low Battery	Replace all batteries with fresh batteries; do not use a combination of a fresh battery and a drained battery
Noisy ECG or SPO2 signal	The device is operated in electrically noisy environment (near generators, big transformers, big motors)	Do not operate the device in the mentioned environments.
Noisy ECG or SPO2 signal	Motion artifact. The user/patient is moving/doing exertion of major muscles	The patient/user should keep still when using the device.
Noisy or no ECG or SPO2 signal	One or all of the electrodes are not connected or electrode-skin contact is poor SPO2 sensor is not properly attached to the patient	Check the electrodes. See to it that the electrodes have not dried out during storage. Check that the SPO2 sensor is properly attached to the patient.
Noisy or no ECG or SPO2 signal	Cable and connector assembly is not properly connected to the i-Viewer CU-PH2.	Check the connection between the ECG cable and connector assembly and the i-Viewer CU-PH2.
Faulty connection when using the IrDA port	IrDA port filter is contaminated with dirt	Clean the IrDA port filter as suggested in the Cleaning section of this manual

6.4 Device Life

The i-Viewer CU-PH2's device life is dependent on the useful lives of its components. When minor components go out of service, they can be replaced in designated service centers. The flash memory device where the program is stored has a maximum life of 20 years. When this period elapses, the memory device will have to be replaced and the system program will have to be downloaded again.

7. SAFETY CONSIDERATIONS

The user must be aware of the following safety considerations when operating the i-Viewer CU-PH2.

These safety considerations had been stated in other parts of this Manual. These are repeated here for emphasis and easy reference.

The safety concerns are labeled according to the seriousness of the resulting injuries when an accident involving these safety concerns occurs.

a) **WARNING** – conditions, hazards, or unsafe practices that can result in personal injury.
b) **CAUTION** – conditions, hazards, or unsafe practices that can result in minor personal injury, damage to the i-Viewer CU-PH2, or loss of data stored in the device.
c) **NOTICE** - Notes items that are important during installation, operation, or maintenance of the device.

GENERAL SAFETY CONSIDERATIONS	
SAFETY LEVEL	**POSSIBLE DANGERS and HAZARDS**
NOTICE	The user should understand this User's Manual well before attempting to use this device.
NOTICE	Make sure that the disposable electrodes are not yet past their expiration date. Do not use electrodes that are past their expiration dates.
NOTICE	If you are using electrodes that are packaged in a pouch, close and reseal the pouch after getting the electrodes that you need. Resealing the packaging pouch will help prolong the life of the electrodes.
NOTICE	Do not reuse disposable electrodes. These are for one time use only.
NOTICE	During ECG data acquisition, the patient or user should keep still to avoid having motion artifacts in the ECG signal. Motion artifact is caused by electrical interference from muscular activity
NOTICE	The i-Viewer CU-PH2 will indicate only the heart rate (in bpm) and whether the ECG signal is normal or not. It will not analyze the ECG signal for arrhythmias or other heart abnormalities. However, the device keeps an accurate record of the ECG which can be used by a qualified physician for analysis.
NOTICE	The i-Viewer CU-PH2 is capable of acquiring any of the leads (Leads I, II, III, aVL, aVF, aVL, and V) without having the position of the electrodes changed. However, only the chosen lead is acquired, analyzed, and recorded at any given time.
NOTICE	Used consumables (disposable electrodes, batteries) should be disposed of in accordance with local regulations
⚠CAUTION	Do not immerse any part of the i-Viewer CU-PH2 in fluids Do not let any fluid enter the case of the device. Do not spill liquids on the case of the device. Do not use strong, acetone-based cleaners in cleaning the device. Do not use abrasive materials in cleaning the unit, especially the LCD display and the infrared filter on the IrDA port. Do not sterilize the i-Viewer CU-PH2.
⚠WARNING	There are no user-serviceable parts inside the i-Viewer CU-PH2. For those conditions not specified in this troubleshooting guide, please consult the manufacturer or its authorized representatives.

GENERAL SAFETY CONSIDERATIONS	
SAFETY LEVEL	**POSSIBLE DANGERS and HAZARDS**
⚠WARNING	The manufacturer will not be liable for any damage or injury that may arise from an attempt to repair the device beyond what is described in this troubleshooting guide.
NOTICE	Attempts to repair the i-Viewer CU-PH2 beyond what is described in the troubleshooting guide will make the warranty null and void.
NOTICE	Do not operate the device in electrically noisy environments (near big motors, generators, or power transformers) as these will interfere with the signals being acquired.
NOTICE	Some electrode conducting gel may cause skin irritation on some patients/users. If this occurs, switch to electrodes with different conducting gel.
⚠WARNING	Turn the device OFF before removing the batteries during battery replacement
⚠WARNING	Do not short the electrodes when the device is ON
⚠WARNING	If the i-Viewer CU-PH2 is powered by the AC/DC adapter, do not use the it alongside with high frequency electrocautery equipment. The i-Viewer CU-PH2 may be used alongside with high frequency electrocautery equipment if it is powered by batteries.
⚠WARNING	The device is designed to be used only in the acquisition and processing/display of surface ECG's. The device is not to be used in direct cardiac application (i.e. applied directly to the heart during open chest operations)
NOTICE	The device will issue a “LEADS OFF” text prompt on the LCD when the leads are off. The leads are off when the pads are not properly connected or the cable and connector assembly is damaged
NOTICE	The IrDA transceiver is tested and certified by its manufacturer to conform with the provisions of IEC60825-1

8. DATA MANAGEMENT AND REVIEW

When the i-Viewer CU-PH2 is turned ON, the data is automatically saved in its nonvolatile, internal memory. The data is then available for review and transfer to external devices.

Data is stored in the memory of the device in 60-minute memory partitions. There are 10 memory partitions for a total recording time of 600 minutes. When the device is operated continuously for more than 60 minutes, it automatically saves the data in the next memory partition.

When all of the memory partitions are full, turning the device ON makes it operate without saving ECG data.

9. SPECIFICATIONS

ECG	Input cable		Lead I, II, III, aVL, aVR, aVF, V With 5 Cable Electrodes
	Heart Rate		30~300 bpm
	Input voltage		0.1 mV ~ 5.5mV
	Bandwidth		0.4 to 40Hz
	ECG vertical scales		5, 10, 20mm/mV
SpO2	Pulse Rate		20 ~ 250 bpm ±3bpm
	Saturation		70 ~ 100 % SpO2 ±3%
	Perfusion		0.2%
Device Classification	Type CF Defibrillation protected		
Nellcor Sensor DS100A	Wavelength		Near 660 nm and 890 nm
	Power		Not exceeding 15 mW
Alarm	Heart Rate Alarm		Alarms when the input ECG rate is outside the limits defined by the user.
	SpO2 Alarm		Alarms when the SPO2 value is outside the limits defined by the user.
Display	LCD		4” Mono LCD
	Sweep speed		25mm/s, 50mm/s
	Viewing time		3.2seconds
	Back-light		Electroluminescent backlight.
Data Recording capacity	600 minutes		
Power	Disposable Battery Pack	Type	Alkaline AA BAT 4ea
		Capacity	Up to 10 hours
	Adaptor		DC 12V 3.6A
Communication	UART		
	IrDA		
Environmental	Operating Temperature		5°C to 40°C
	Storge Temperature		-40°C to 70°C
	Operating Humidity		5% to 95% non-condensing
	Operating Altitude		1060 to 500 mbar pressure
Dimensions	108 x 133 x 38 (W x L x H)		
Weight	275g (Battery, ECG Cable)		

CU Medical Systems, Inc.

Address
Medical Industry Park
1720-26 Taejang-dong, Wonju-si,
Kangwon-do, Korea

TEL:
+82-33-747-7657

FAX:
+82-33-747-7659

HOMEPAGE:
http://www.cu911.com

E-mail:
admin@cu911.com

Medical Systems, Inc.